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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,035	02/19/2002	Eliso Quintanilla Almagro	Q64417	3663

7590 02/17/2004

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,035	ALMAGRO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 32-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 32-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed November 17, 2003 is acknowledged and has been entered. Claims 32-40 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 103

Claims 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 2002/0164374) in view of Bosca et al. (Age, 1997), Deshpande et al. (Med. Sci. Res., 1997), and Quiles et al. (BioFactors, 1998), with evidence provided by Tsuda et al. (Atherosclerosis, 1996), for the reasons set forth in the previous Office action which are restated below.

Jackson et al. teach a pharmaceutical composition (polymeric delivery systems) containing curcumin (obtained from tumeric - i.e., *Curcuma longa*) as an active ingredient therein for treating vascular diseases (e.g., obstructed vessels) such as cardiovascular diseases including atherosclerosis (see, e.g., paragraph [0097] - [0103], [0159], [0229]-[0231], [0236], and claims 20-21). Jackson et al. further teach that, as part of the chain of events leading to the formation of obstructive atherosclerotic vascular plaques and narrowing of the vessels, local concentrations of fibrinogen increase (see, e.g., paragraph [0113]).

Each of the cited secondary references teach the administration of a pharmaceutical aqueous alcoholic extract of *Curcuma longa* rhizomes (which expressly or admittedly contain one or more inherent curcuminoid compounds therein including curcumin) to humans or to rabbits. Each of the secondary references also expressly teach that the *Curcuma* extracts are

useful for treating and/or preventing coronary heart disease such as arteriosclerosis (see entire documents including *Materials and Methods* of each). Please note that since all mammals including humans and rabbits are susceptible to fibrinogen diseases (i.e., no one is immune from these afflictions), the referenced administered humans/rabbits meet the claim limitations with respect to the claimed administered mammal (a mammal in need of having their plasma fibrinogen reduced). Further, as evidenced by Tsuda et al., elevated plasma fibrinogen is known to progress atherosclerosis (an extremely common form of arteriosclerosis) and to be one of the risk factors for the occurrence of cardiovascular disease (see, e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the curcumin-containing pharmaceutical composition taught by Jackson et al. to a subject suffering from a cardiovascular disease such as atherosclerosis, including atherosclerosis involving vascular plaque formation related to elevated fibrinogen levels (as disclosed by Jackson et al.; and as evidenced by Tsuda et al. - is well known in the art to be associated with the progression of atherosclerosis/cardiovascular disease), based upon the beneficial teachings provided by Jackson et al. It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made administer an ethanolic and/or aqueous ethanolic extract of *Curcuma longa* rhizomes to such a subject based upon the beneficial teaching provided by the secondary references with respect to the use of *Curcuma longa* rhizome extracts (which expressly and/or admittedly contain curcumin as well as other curcuminoids therein) for such purpose.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants' arguments with respect to the USC 103 rejection above have been carefully considered but are not deemed to be persuasive of error in the rejection.

Applicants argue that although Jackson et al. may disclose a pharmaceutical composition comprising curcumin (from *Curcuma longa*) as an active ingredient for treating vascular diseases, such as cardiovascular diseases like atherosclerosis and that increased local fibrinogen concentrations lead to the formation of atherosclerotic plaques, when they refer to curcumin, Jackson et al. indicate curcumin's effect is as a potent antioxidant and its properties as hypolipedemic and hypercholesterolemic, and thus it would not be obvious to one skilled in the art to administer the curucmin-containing pharmaceutical composition taught by Jackson et al. to reduce fibrinogen levels. However, the express teachings of Jackson et al. with respect to the well known correlation between fibrinogen concentrations and the formation of atherosclerotic plaques, is not suggestive of precluding treating atherosclerosis caused thereby (i.e., not suggestive of precluding one of ordinary skill in the art from administering an effective amount of curcumin and/or *Curcuma longa* rhizome extract preparations to a subject suffering from atherosclerosis caused by elevated plasma fibrinogen levels). Further, the cited art, as a whole, would not lead one of ordinary skill in the art to preclude treating atherosclerosis, whatever the underlying cause(s) thereof, including atherosclerosis caused by increased plasma fibrinogen concentrations, which (as discussed above) is notoriously well known in the medical art to be commonly associated with and a risk factor of atherosclerosis.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

Christopher R. Tate
Primary Examiner, Group 1654